DRUG REFORM AND THE PUBLIC INTEREST:
A CONGRESSIONAL VIEWPOINT

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GOOD MORNING. IT IS INDEED AN HONOR FOR ME TO BE HERE AT THE TWENTY-SECOND ANNUAL MEETING OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION. I WANT TO GIVE SPECIAL THANKS TO LEWIS A. ENGMAN, PMA'S PRESIDENT, AND TO YOUR BOARD OF DIRECTORS AND STAFF FOR PROVIDING THIS OPPORTUNITY FOR ME TO MEET WITH YOU TODAY.

YOU HAVE HELD ANNUAL MEETINGS OF THIS KIND FOR OVER TWO DECADES. I'M SURE THAT EACH YEAR'S MEETINGS FAITHFULLY CRONICLE TREMENDOUS CHANGES IN YOUR INDUSTRY. AS WE LOOK AT THIS TWO DECADE PERIOD, SINCE THE LATE 1950'S WE HAVE WATCHED NOT AN EVOLUTION, BUT IN A SENSE, A <u>REVOLUTION</u> WITH DYNAMIC AND EXICTING CHANGES IN THE:

<u>BURGEONING CREATIVITY OF BIOMEDICAL RESEARCH, AS A RESULT OF UNPRECEDENTED INVESTMENTS OF CAPITAL</u> BY PRIVATE INDUSTRY, THE FEDERAL GOVERNMENT AND PRIVATE PHILANTHROPY....

....IF WE HAD A SCIENTIFIC OLYMPICS, AS WE DO FOR SPORTS, WE ALL KNOW AMERICAN INDUSTRY WOULD WALK AWAY WITH "THE GOLD" FOR ITS UNPRECEDENTED INVESTMENT IN THE DEVELOPMENT OF NEW DRUGS, NEW MEDICAL DEVICES, AND NEW TECHNOLOGY...

....MORE CONSUMER FOOD AND DRUG PRODUCTS, IN MORE VARIATIONS, SIZES OR DOSES ARE AVAILABLE THAN EVER BEFORE IN THE AMERICAN MARKETPLACE. THE PRODUCTIVITY OF THE FOOD AND DRUG INDUSTRIES CONTINUES TO BE HIGHER THAN MANY OTHER KEY SEGMENTS OF OUR ECONOMY.

...AND FINALLY, WE HAVE WATCHED SCIENCE BECOME ONE OF OUR HIGHEST EDUCATIONAL PRIORITIES. CONCERN WITH "KEEPING OUR EDGE" IN THE INTERNATIONAL COMMUNITY HAS MEANT SCIENTIFIC TRAINING IS GIVEN TREMENDOUS IMPORTANCE IN SCHOOL CURRICULA, IN COLLEGE AND GRADUATE SCHOOL ENTRANCE REQUIREMENTS, AND IN THE FUNDING OF AMERICA'S GREATEST UNIVERSITIES AND MEDICAL CENTERS THAT DEVOTE FACULTY AND LABORATORY RESOURCES TO SCIENTIFIC RESEARCH.

THIS EXPLOSION OF SCIENTIFIC RESEARCH AND MEDICAL TECHNOLOGY HAS HAD A TREMENDOUS IMPACT ON OUR SOCIETY. IT'S NOT OFTEN SAID, BUT IT NEEDS SAYING: THANKS TO THE ENORMOUS INVESTMENT WE WERE WILLING TO MAKE IN DRUG RESEARCH, TREMENDOUS ADVANCES IN PUBLIC HEALTH HAVE BEEN MADE. LET ME JUST POINT OUT <u>FOR ONE DISEASE</u> ACHIEVEMENTS WE HAVE MADE IN A FEW SHORT YEARS.

CANCER IS THE MOST FEARED AND MOST PAINFUL OF ALL THE MAJOR DISEASE KILLERS IN AMERICA TODAY. IT WILL STRIKE ONE OUT OF EVERY FOUR AMERICANS, AND TWO OUT OF

EVERY THREE FAMILIES. WHEN THE PMA FIRST BEGAN HOLDING ITS ANNUAL MEETINGS IN THE LATE 1950'S, A DIAGNOSIS OF CANCER WAS -- FOR MANY PATIENTS -- LIKE HEARING A DEATH SENTENCE.

BUT THAT IS NO LONGER TRUE TODAY. WHY? BECAUSE THE DRUG INDUSTRY, THE NATIONAL INSTITUTES OF HEALTH, AND PRIVATE GROUPS SUCH AS THE AMERICAN CANCER SOCIETY, WORKED IN A COOPERATIVE EFFORT TO EFFECTIVELY CONTROL, AND WHERE POSSIBLE CURE THIS DISEASE. THE SUCCESS OF THIS COOPERATIVE EFFORT IS JUST NOW BECOMING APPARENT IN OUR PUBLIC HEALTH STATISTICS.

RECENTLY DEVELOPED CANCER DRUGS AND THERAPIES HAVE SUBSTANTIALLY IMPROVED THE SURVIVAL RATES FOR 7 OF THE 10 MAJOR FORMS OF CANCER. ALMOST 60% OF THE MORE THAN ONE MILLION AMERICANS WHO WILL DEVELOP CANCER THIS YEAR CAN EXPECT TO BE CURED, ACCORDING TO FIGURES RELEASED JUST TWO WEEKS AGO BY THE NATIONAL CANCER INSTITUTE.

WE HAVE BEEN PARTICULARLY SUCCESSFUL IN TREATING CANCERS THAT STRIKE CHILDREN AND YOUNG ADULTS -- WHICH IN THE PAST WERE SO TRAGIC BECAUSE FAMILIES FELT SENSELESSLY ROBBED ON AN INDIVIDUAL BEFORE HIS OR HER LIFE WAS MORE THAN JUST BARELY UNDERWAY. SCIENTIFIC RESEARCH, NEW DRUGS, AND THERAPIES HAVE ACTUALLY REVERSED THE GLOOMY ODDS OF YEARS AGO WHEN A CHILD WAS DIAGNOSED WITH LEUKEMIA, HODGKIN'S DISEASE OR BONE CANCER.

WE HAVE SEEN OTHER IMPRESSIVE GAINS IN HEALTH STATUS IN THE PAST FEW YEARS ATTRIBUTABLE IN PART TO IMPROVED MEDICATION AND DIAGNOSTIC TECHNIQUES:

* BETWEEN 1950 AND 1977, THE MORTALITY RATE FOR CHILDREN AGED ONE TO 14 WAS CUT IN HALF.
* A BABY BORN IN THIS COUNTRY TODAY CAN BE EXPECTED TO LIVE MORE THAN 73 YEARS ON AVERAGE, WHILE A BABY BORN AT THE BEGINNING OF THIS CENTURY COULD BE EXPECTED TO LIVE ONLY 47 YEARS.
* DEATHS DUE TO HEART DISEASE DECREASED IN THE UNITED STATES BY 22 PERCENT BETWEEN 1968 AND 1977.
* DURING THE PAST DECADE THE EXPECTED LIFE SPAN FOR AMERICANS HAS INCREASED BY ANOTHER 2.7 YEARS.

WHAT HAS MADE THESE REMARKABLE GAINS POSSIBLE? IT IS THE JOINT EFFORT OF GOVERNMENT, BUSINESS, AND PHILANTHROPY TO IMPROVE LIVING CONDITIONS AND SANITATION, AS WELL AS TO DEVELOP VACCINES AND ANTIBIOTICS WHICH KEPT SO MANY DREADED DISEASES FROM TAKING THEIR TOLL IN PREMATURE DEATHS.

ALL OF US INVOLVED IN THE HEALTH CARE FIELD WANT TO SEE THIS PROGRESS CONTINUE. AND WHILE THE HEALTH OF OUR ECONOMY IS FAR DIFFERENT THAN IT WAS DURING THE YEARS OF THESE GREAT ACCOMPLISHMENTS, THE CHALLENGE IN THE 1980'S IS A CONTINUING ONE TO FIND INCENTIVES FOR INDUSTRY TO

CARRY ON VITAL RESEARCH AND DEVELOPMENT. I WANT YOU TO KNOW THAT YOU HAVE MY COMMITMENT, AS A REPRESENTATIVE IN A SENSE FROM GOVERNMENT, TO WORK WITH YOU TO CREATE A CLIMATE THAT NURTURES PRODUCTIVE RESEARCH AND DEVELOPMENT OF NEW DRUGS. SCIENTIFIC BREAKTHROUGHS IN THE TREATMENT AND CURE OF HEARTBREAKING DISEASES ARE CLEARLY IN THE PUBLIC INTEREST. AND WE MUST BE MORE AWARE TODAY THAN EVER BEFORE, THAT GOVERNMENT EVEN ACTING WITH GOOD INTENTIONS, CAN DESTROY INCENTIVES IN OUR PRIVATE SECTOR -- THROUGH EXCESSIVE AND MINDLESS REGULATION AND OTHER WAYS, TO LIVE UP TO WHAT IS IN ITS OWN AND THE PUBLIC'S BEST INTEREST.

I STRESS THE MUTUAL COOPERATION OF GOVERNMENT AND INDUSTRY BECAUSE I THINK TOO OFTEN OUR RELATIONSHIP HAS BEEN OTHER THAN ONE OF TEAMWORK. JUST LOOK AT THE SUCCESS OF MASS IMMUNIZATION PROGRAMS AS AN EXAMPLE OF WHAT INDUSTRY AND GOVERNMENT CAN DO TOGETHER TO IMPROVE PUBLIC HEALTH. SCIENTIFIC BREAKTHROUGHS LED TO THE DEVELOPMENT OF POLIO VACCINE. THE INGENUITY AND KNOW-HOW OF AMERICAN INDUSTRY DESIGNED A MANUFACTURING PROCESS TO PRODUCE MILLIONS OF BATCHES OF THAT VACCINE IN AN UNPRECEDENTED SHORT TIME. FEDERAL, STATE AND LOCAL GOVERNMENT AGENCIES, PUBLIC HEALTH DEPARTMENTS, MEDICAL SOCIETIES AND VOLUNTEERS

WORKED TOGETHER TO SUCCESSFULLY ERADICATE THIS HEARTBREAKING CRIPPLER. TODAY WE HAVE A NAME FOR ALL THIS: WE CALL IT "TECHNOLOGY TRANSFER". BUT BACK IN THE 1950'S, IT WASN'T CALLED ANYTHING, EXCEPT PERHAPS MIRACULOUS.

AN ANNUAL MEETING OF THIS KIND NOT ONLY LOOKS BACKWARD TO SEE HOW FAR WE HAVE COME, BUT ALSO FORWARD TO SET GOALS FOR YOUR INDUSTRY IN THE DECADE AHEAD. LET ME ADDRESS SOME OF WHAT I BELIEVE ARE KEY ISSUES FOR DRUG DEVELOPMENT, DRUG REGULATION, AND DRUG LAW REFORM.

FIRST, THERE ARE CERTAIN POPULATION GROUPS THAT URGENTLY NEED TO HAVE THEIR SPECIAL NEEDS ADDRESSED. SMALL PATIENT POPULATIONS WITH RARE DISEASES CONTINUE TO FIND THEIR MEDICAL NEEDS INADEQUATELY SERVED BECAUSE DEVELOPING, TESTING AND MARKETING A NEW DRUG IS SO COSTLY. I DO NOT KNOW THE ANSWER TO THIS PROBLEM, BUT I THINK THERE ARE SOME GOOD IDEAS THAT DESERVE CONSIDERATION AND I WOULD LIKE TO RAISE THEM WITH YOU HERE TODAY. SHOULD THE FEDERAL GOVERNMENT (EITHER AT THE NATIONAL INSTITUTES OF HEALTH OR AT THE FOOD AND DRUG ADMINISTRATION) ESTABLISH A PHARMACOLOGY CENTER FOR THE DEVELOPMENT OF MEDICATIONS FOR SMALL PATIENT POPULATIONS? ALTERNATIVELY, SHOULD INDUSTRY IN EFFECT "TITHE" ITSELF, AND EARMARK A SIGNIFICANT PORTION OF PROFITS FOR RESEARCH ON DRUGS WITH NO PROFIT POTENTIAL? I SHARE THE CONCERN OF MANY WHO WONDER WHETHER THE NEEDS FOR A SMALL PATIENT POPULATION SEEM TO GET LOST IN THE BIGGER PICTURE.

ANOTHER POPULATION GROUP THAT MERITS SPECIAL ATTENTION BY THE DRUG INDUSTRY IN THE 1980'S IS NOT A SMALL ONE AND IS CLEARLY A GROWING ONE, AMERICA'S ELDERLY. WE ARE SEEING WHAT IS CALLED THE "GREYING OF AMERICA". EACH YEAR ABOUT 1.8 MILLION AMERICANS REACH THE AGE OF 65, A NET INCREASE OF ABOUT 1,510 A DAY.

BUT WITH THESE YEARS COMES THE INCREASING LIKELIHOOD OF CHRONIC ILLNESS, DISABILITY , AND PAIN. SOME OF THE DIFFICULTIES OF OLD AGE CAN BE MADE LESS ARDUOUS AS YOU CONTINUE TO PLACE A GREATER EMPHASIS ON THE DEVELOPMENT OF NEW DRUGS AND DEVICES SO NEEDED BY THEM.

MY CONGRESSIONAL DISTRICT HAS THE SECOND MOST ELDERLY CONSTITUENCY OF ANY IN THE UNITED STATES -- (RIGHT AFTER ST. PETERSBURG, FLORIDA). MY CONSTITUENTS WRITE AND TELL ME THAT THEY WOULD LIKE TO SEE THESE DEVELOPMENTS IN THE YEARS AHEAD IN ADDITION TO NEW BREAKTHROUGHS:

-- DRUGS PRICED COMPETITIVELY, AND MORE COMPREHENSIVE INSURANCE COVERAGE FOR DRUGS, MEDICAL DEVICES AND THERAPIES ADMINISTERED IN OUT-PATIENT SETTINGS.
-- FULL DISCLOSURE OF POSSIBLE SIDE EFFECTS OF DRUGS AND MORE DETAILED DOSAGE INFORMATION. MANY ELDERLY PATIENTS REPORT THAT DRUG DOSAGES ACCEPTABLE FOR OTHER AGES SEEM INAPPROPRIATE FOR THEM.

-- MORE INFORMATION ON HOW MEDICATIONS INTERACT WITH EACH OTHER. MANY ELDERLY TAKE TWO, THREE OR FOUR DIFFERENT PRESCRIPTIONS SIMULTANEOUSLY.

AS WE LOOK AT HEALTH CARE IN THIS COUNTRY, WE NEED TO LOOK AT BOTH THE SUPPLY AND DEMAND SIDE OF THE EQUATION. IF HEALTH CARE IS GETTING TO BE MORE COSTLY TO DELIVER, WE MUST RECOGNIZE THAT ONE OF THE MOST CONTRUCTIVE AND COST-EFFECTIVE APPROACHES IS FOR PEOPLE TO TAKE A GREATER RESPONSIBILITY IN THEIR OWN HEALTH CARE -- THROUGH A MORE HEALTHFUL DIET AND LIFE-STYE AS WELL AS THROUGH APPROPRIATE SELF-MEDICATION.

SOME DREADED DISEASES WHICH IN THE PAST HAVE TAKEN SUCH AN ENORMOUS PERSONAL AND FINANCIAL TOLL HAVE BEEN ELIMINATED OR CONTROLLED BY DRUGS. THE COSTS THAT WILL BE SAVED THAT OTHERWISE WOULD GO FOR TREATING POLIO OR SMALL POX, PLACING PEOPLE IN MENTAL HOSPITALS OR OTHER SANITORIUMS, OR TREATING AN ADVANCED DISEASE NOW DISCOVERED AT AN EARLY STAGE BY A MEDICAL DEVICE, FAR EXCEED AND ARE FAR MORE CONSISTENT WITH OUR VALUES THAN ALL THE MONEY THAT MIGHT BE SAVED BY PLACING ARTIFICIAL CEILINGS ON HOSPITAL OR OTHER HEALTH COSTS.

WHILE THE DRUG INDUSTRY AMOUNTS TO ONLY A SMALL FRACTION OF THE ENORMOUS AMOUNT WE SPEND ON HEALTH CARE DELIVERY, IT OFFERS THE HOPE OF ASSISTING OUR SOCIETY TO HOLD DOWN MUCH OF THOSE COSTS IN THE FUTURE.

LET ME BRIEFLY OUTLINE WHAT FOOD AND DRUG ISSUES CONGRESS IS NOW WORKING ON FOR THIS SESSION WHICH MAY BE OF SPECIAL INTEREST TO YOU.

AN INFANT FORMULA ACT OF 1980 WILL, IF ENACTED, FURTHER ASSURE THE SAFETY OF BABY FORMULA WHICH IS USED AS THE SOLE SOURCE OF NOURISHMENT FOR CHILDREN DURING THE CRUCIALLY IMPORTANT FIRST YEAR OF THEIR DEVELOPMENT. THE LEGISLATION WAS INTRODUCED IN RESPONSE TO A VERY UNFORTUNATE INCIDENT LAST SUMMER WHEN ONE PRODUCT LINE FAILED TO INCLUDE AN INGREDIENT ESSENTIAL FOR INFANTS TO THRIVE. OVER 100 INFANTS MAY HAVE BEEN HARMED BY THIS PRODUCT.

THE QUESTIONS RAISED IN CONGRESSIONAL HEARINGS ON THIS PRODUCT WERE:

-- SHOULD A SOLE SOURCE OF NOURISHMENT PRODUCT GO ON THE SHELVES OF THE SUPERMARKET WITHOUT THOROUGH PRE-MARKETING TESTING?
-- WHO SHOULD DO THAT TESTING?
-- HOW CAN A DEFECTIVE FOOD OR DRUG PRODUCT BE RECALLED IMMEDIATELY -- PARTICULARLY IF IT IS NOT ADULTERATED?

-- WILL STRICTER REGULATION BY THE FEDERAL GOVERNMENT OF INGREDIENTS, INGREDIENT LABELING AND INGREDIENT PRE-MARKET TESTING STIFLE INNOVATION IN DEVELOPING NEW PRODUCTS?

FOR THE HEALTH AND THE ENVIRONMENT SUBCOMMITTEE, WORK ON THIS ISSUE WAS A VALUABLE EDUCATION AND INTRODUCTION TO FOOD AND DRUG ISSUES. REMEMBER THAT ABOUT HALF OF THE MEMBERS OF THE SUBCOMMITTEE JOINED THE PANEL IN THIS CONGRESS. THAT MEANS, THAT OVER HALF MY SUBCOMMITTEE WAS NOT IN THE CONGRESS WHEN WE DRAFTED THE MEDICAL DEVICE LEGISLATION A FEW SHORT YEARS AGO, OR EVEN WHEN WE STARTED CONSIDERATION OF THE ADMINISTRATION'S DRUG BILL IN THE LAST CONGRESS WHEN PAUL ROGERS WAS SUBCOMMITTEE CHAIRMAN.

WHAT AN EXCELLENT BEGINNING. REPRESENTATIVES OF THE INDUSTRY COULD NOT HAVE BEEN MORE COOPERATIVE AND CONSTRUCTIVE. TOGETHER, WE HAVE DRAFTED LEGISLATION TO DEAL WITH THIS PROBLEM WHICH I EXPECT WILL HAVE THE COMPLETE SUPPORT OF EVERYONE CONCERNED.

A SECOND ISSUE THAT THE HEALTH AND THE ENVIRONMENT SUBCOMMITTEE HAS WORKED ON IS FEDERAL REIMBURSEMENT FOR PNEUMONIA VACCINE INNOCULATIONS. PNEUMONIA IS RESPONSIBLE FOR A GREAT MANY NEEDLESS PREMATURE DEATHS AMONG OUR ELDERLY; PARTICULARLY DURING THE FLU SEASON EACH YEAR. SINCE THE TECHNOLOGY IS NOW AVAILABLE TO ARREST THIS NEEDLESS KILLER, OUR COMMITTEE HAS DETERMINED THAT THE FEDERAL GOVERNMENT SHOULD OFFER REIMBURSEMENT UNDER MEDICARE FOR THE VACCINE.

UNDER THE LEGISLATION, MEDICARE WILL REIMBURSE FOR PNEUMONIA VACCINE WHEN ADMINISTERED BY A PHYSICIAN IN AN OUT-PATIENT SETTING. TRADITIONALLY, AS YOU KNOW, MEDICARE HAS REIMBURSED FOR DRUGS IN IN-PATIENT SETTINGS, SO THIS WOULD BE AN IMPORTANT PUBLIC POLICY CHANGE IN OUR ENTITLEMENT PROGRAM FOR THE ELDERLY.

I FULLY EXPECT THAT THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT WILL LAUNCH SEVERAL WEEKS OF HEARINGS THIS SPRING AND SUMMER ON A REWRITE OF THE DRUG SECTION OF THE FOOD DRUG AND COSMETIC ACT. WHILE THE SCOPE OF THESE HEARINGS WILL BE AS BROAD AS THE DRUG LAWS THEMSELVES, FIRST INTRODUCED IN THE 95TH CONGRESS, I DO NOT ANTICIPATE ENACTMENT OF A COMREHENSIVE PROPOSAL THIS YEAR. UNLIKE THE SENATE COMMITTEE, WE HAVE NOT HAD THE YEARS OF INVOLVEMENT WITH THIS COMPLEX AND IMPORTANT AREA. I DO NOT SEE A MAJOR COMPREHENSIVE CHANGE IN THE LAW WITH SO MANY MAJOR CONSEQUENCES TO IT, WITH OUT OUR GETTING MORE THOROUGHLY FAMILIAR WITH THE WHOLE AREA.

WE MAY, ON THE OTHER HAND, TAKE CERTAIN PORTIONS OF THE DRUG REFORM ACT PROPOSAL, AND TAKE ACTION ON THEM THIS YEAR, RATHER THAN UNDERTAKING A MASSIVE REWRITE WHICH HAS LITTLE LIKELIHOOD OF ENACTMENT.

THE HEARINGS I LOOK FORWARD TO CONDUCTING THIS SUMMER ON DRUG REFORM WILL REVIEW CURRENT PROPOSALS ON THIS ISSUE. BUT, SINCE I AM SO COMPLETELY CONVINCED THAT ONE OF OUR UNFORTUNATELY NEGLECTED AREAS OF CONGRESSIONAL RESPONSIBILITY IS THAT OF OVERSIGHT OF EXISTING LAW AND THE AGENCIES SET UP TO ENFORCE AND ADMINISTER IT, WE WANT TO TAKE A CLOSE LOOK AT HOW FDA DOES ITS JOB TO PROTECT THE PUBLIC AND SPEEDILY MAKE AVAILABLE TO IT NEW INNOVATIONS.

ANY LEGISLATION TO REFORM OUR DRUG LAWS MUST ACCOMPLISH A NUMBER OF IMPORTANT GOALS.

FIRST, WE MUST IMPROVE THE SPEED AND EFFICIENCY OF OUR DRUG APPROVAL PROCESS WHILE ALWAYS ASSURING THE SAFETY AND EFFICACY OF EVERY NEW DRUG. THIS DELICATE BALANCE MUST BE ACHIEVED WHILE WE ENCOURAGE INCREASED INVESTMENT IN RESEARCH AND DEVELOPMENT AND AN INCREASED RATE OF INNOVATION IN NEW DRUGS.

OUR DRUG APPROVAL PROCESS MUST BE PREDICTABLE AND DEPENDABLE IN BOTH THE IND AND NDA PHASES. IT MUST GET IMPORTANT BREAKTHROUGH DRUGS ON THE MARKET MORE QUICKLY, BECAUSE THAT IS IN THE PUBLIC'S INTEREST. THE FDA MUST CONSTANTLY STRIVE TO IMPROVE ITS MANAGEMENT OF THE NEW DRUG APPROVAL PROCESS AND TO INSURE THAT ADEQUATE PERSONNEL ARE AVAILABLE TO EXPEDITE IT. THEY HAVE A DIFFICULT JOB TO DO, WHATEVER THE STATUTE MAY PROVIDE, BECAUSE THEY MUST

MAKE DECISIONS THAT INVOLVE A TRADE-OFF OF RISKS AND BENEFITS IN A WORLD WHERE THERE IS NO SUCH THING AS ZERO RISK AND WHERE SCIENTIFIC JUDGEMENTS ARE NEVER COMPLETE AND THE BEST ONES CAN BE WRONG. BUT TO HELP THEM, WE MUST IMPROVE COMMUNICATION IN ALL STAGES OF THE IND/NDA PROCESS. WE MUST BREAK OUR ATTACHMENT TO INEFFECTIVE REGULATORY REQUIREMENTS AND SEEK TO SIMPLIFY OUR REGULATORY PROCESS.

OUR DRUG LAWS SHOULD ATTEMPT TO RETAIN THE PUBLIC'S CONFIDENCE IN THE SAFETY AND EFFICACY OF OUR DRUGS, BOTH WHEN THEY ARE INTRODUCED AND THROUGHOUT THE LIFE OF THE DRUG. CONSUMERS ASSUME THERE IS CONSTANT SURVEILLANCE OF THE DRUGS THEY DEPEND UPON SO FAITHFULLY.

THE FIRST STEP TOWARD DRUG REGULATION REFORM CAN BE TAKEN WITHOUT LEGISLATION. WHAT CONSUMERS, GOVERNMENT AND YOUR INDUSTRY NEED MOST OF ALL IS IMPROVED COMMUNICATION AND A DETERMINATION TO WORK OUT SOLUTIONS ACCEPTABLE TO AND IN THE INTEREST OF ALL PARTIES.

I AGREE WITH THE STATEMENT OF YOUR CHAIRMAN THAT "IN THE LONG RUN, THERE ARE NO IMPORTANT ISSUES IN WHICH THE INDUSTRY'S INTERESTS AND THOSE OF THE GENERAL PUBLIC'S DIVERGE."

WE MUST AVERT THE PROBLEMS TO WHICH TUNNEL VISION LEAD WHEN WE FOCUS ON ISSUES EXCLUSIVELY FOR THE NARROW OR SHORT-TERM OBJECTIVE.

GOVERNMENT AND INDUSTRY HAVE BEEN ADVERSARIES FOR TOO LONG -- AND I EXPECT THERE WILL BE TIMES IN THE FUTURE WHEN THIS WILL BE NECESSARY. BUT, OUR MUTUAL AND SHARED GOAL -- THE PUBLIC'S INTEREST SHOULD BE KEPT IN MIND AS WE WORK TOGETHER FOR NEEDED IMPROVEMENT AND BENEFICIAL CHANGES.